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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,071	SWAIN ET AL.	
	Examiner	Art Unit	
	AMBER D. STEELE	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2010 and 17 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *176-179* is/are pending in the application.

4a) Of the above claim(s) *177 and 178* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *176 and 179* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-99, 105-108, and 110 were canceled, claims 101-103 and 109 were amended, and new claims 111-124 were added in the amendment to the claims received on June 1, 2006.

The amendment to the claims received on February 16, 2007 amended claims 100-101, 118; canceled claims 102, 114-116; and added new claims 125-140.

The amendment to the claims received on October 9, 2007 canceled claims 100-101, 103-104, 109, 111-113, 117-124, 127, and 130 and amended claims 125 and 129.

The amendment to the claims received on June 12, 2008 amended claim 125, canceled claims 129 and 139-140, and added new claims 141-142.

The amendment to the claims received on January 26, 2009 amended claims 125-126, 128, 131-138, and 142 and canceled claim 141.

The amendment to the claims received on June 11, 2009 amended claims 125 and 142.

The amendment received on August 26, 2009 amended claims 125 and 126 and canceled claims 143-160.

The amendment to the claims received on November 23 and 24, 2009 canceled all prior claims and added new claims 161-168.

The amendment to the claims received on January 20, 2010 canceled claims 161-168 and added new claims 169-175.

The amendment to the claims received on July 29, 2010 canceled claims 169-175 and added new claims 176-179.

Claims 176-179 are currently pending.

Claims 176 and 179 are currently under consideration.

Election/Restrictions

2. Applicant's election of the species of claim 179 in the reply filed on November 17, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 177 and 178 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 17, 2010.

Priority

4. The present application claims status as a CON of 10/115,580 filed April 1, 2002 which is a CON of 09/882,803 filed June 14, 2001 which is a CON of 09/257,821 filed February 25, 1999 which is a CON of 08/720,487 filed September 30, 1996 (now U.S. Patent 5,876,727) which is a CIP of 08/563,673 filed November 28, 1995 (now U.S. Patent 5,760,184) which is a CIP of 08/414,971 filed March 31, 1995.

5. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 10/115,580; 09/882,803; 09/257,821; 08/720,487; 08/563,673; and 08/414,971, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior-filed applications do not provide support for the subgenus/species of a nicotine-Pseudomonas exotoxin conjugate. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Also see In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) and Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). A "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. Therefore, the presently filed application has a priority date of August 22, 2003.

Arguments and Response

6. Applicants contend that the specification is "replete with examples of nicotine as the hapten used in the conjugate" and that working examples of nicotine conjugated to BSA or cholera toxin B are provided. Applicants appear to contend that pseudomonas exotoxin is not part of a laundry list because it is one of seven bacterial toxins described in the specification as potential carriers. However, applicants arguments are not convincing since bacterial toxins are a subgenus of the vast laundry list of carriers contemplated in the specification (see pages 27 and 28 of the originally filed specification).

Withdrawn Objections

7. The objections to claims 169-175 are withdrawn in view of the cancellation of the claims in the amendment received on July 29, 2010.

New Objections

Claim Objections

8. Claim 176 is objected to because of the following informalities: CJ3 $CO(CH_2)_nQCO$ is considered a typographical error (i.e. CJ3 CO $(CH_2)_nCOQ$; please also see claim 178). Appropriate correction is required.

Withdrawn Rejections

9. The rejection of claims 169-175 under 35 U.S.C. 112, first paragraph, regarding scope of enablement is withdrawn in view of the claim amendments received on July 29, 2010.

10. The rejection of claims 169-170 and 173-175 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of the claims in the amendment received on July 29, 2010.

11. The rejection of claims 169-175 under 35 U.S.C. 103(a) as being unpatentable over Walling et al. U.S. Patent 5,164,504 issued November 17, 1992; Swain et al. WO 98/14216 published April 9, 1998; Glenn et al. U.S. Patent 5,980,898 with an effective filing date of November 14, 1996; and Layton et al.., Factors influencing the immunogenicity of the haptenic

drug chlorhexidine in mice, Immunology 59: 459-465, 1986 is withdrawn in view of the claim amendments received on July 29, 2010.

12. The rejection of claims 169-175 under 35 U.S.C. 103(a) as being unpatentable over Ennifar et al. U.S. Patent 6,232,082 issued May 15, 2001 and Layton et al.., Factors influencing the immunogenicity of the haptenic drug chlorhexidine in mice, Immunology 59: 459-465, 1986 is withdrawn in view of the claim amendments received on July 29, 2010.

13. The provisional rejection of claims 169-175 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 88, 90, 103, 106, 108, 109, 128, 130, and 132-149 of copending Application No. 11/472,215 in view of Glenn et al. U.S. Patent 5,980,898 with an effective filing date of November 14, 1996 is withdrawn in view of the abandonment of the application.

Revised Rejections

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 176 and 179 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. This is a **new matter** rejection. Applicants contend that Figure 18 A and B provide support for the presently claimed invention. However, Figures 18 A and 18B do not provide support for the three species as claimed.

16. Claims 176 and 179 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **written description** rejection.

With regard to the written description requirement, the attention of the Applicant is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original) [The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)] (the case is referred to herein as "Lilly").

Additionally, it is noted that written description is legally distinct from enablement: "Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the

enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing University of California v. Eli Lilly & Co.

Although directed to DNA compounds, this Eli Lilly holding would be deemed to be applicable to any compound or a generic of compounds; which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the compound or generic(s). In this regard, applicant is further referred to University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997); "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001); and Univ. Of Rochester v G. D. Searle and Co. 249 F. Supp. 2d 216 (W.D.N.Y. 2003) affirmed by the CAFC on February 13, 2004 (03-1304) publication pending.

Additionally, Lilly sets forth a two part test for written description:

A description of a genus of cDNA's may be achieved by means of a recitation of: a representative number of cDNA's, defined by nucleotide sequence, falling within the scope of the genus OR of a recitation of structural features common to the members of the genus. See Regents of the University of California v. Eli Lilly & Co. 119 F.3d 1559 (Fed. Cir. 1997) at 1569.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d

1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Additionally, Cf. University of Rochester v G.D. Searle & Co., Inc., Monsanto Company, Pharmacia Corporation, and Pfizer Inc., No. 03-1304, 2004 WL 260813 (Fed. Cir., Feb. 13, 2004) held that:

> Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.

In the present instance, the specification discloses only limited examples that are not representative of the claimed subgenus/species of a hapten carrier conjugate comprising nicotine and pseudomonas exotoxin linked via CJ 1, CJ 3, or CJ 11; nor do the claims recite sufficient structural feature(s) which is(are) common to members of the subgenus/species sufficient to demonstrate possession of the subgenus/species.

Applicants' claims encompass a vast number of linkers (i.e. n is an integer). The scope of the claims includes a vast number of components because the linkers are not specifically defined. Furthermore, the specification and claims do not place any limit on the number of components, the types of components, or the manner in which the components might be connected to form a pharmaceutical composition comprising nicotine and pseudomonas exotoxin. Therefore, Applicant is using an inadequately described linker to describe the presently claimed hapten-carrier conjugate. Consequently, there is no teaching that would allow a person of skill in the art

to determine a priori that the Applicant was in possession of the full scope of the claimed invention at the time of filing because there is no common structural attributes that can link together all of the claimed hapten-carrier conjugates.

The general knowledge and level of skill in the art for hapten-carrier conjugates is high, the general knowledge and level of skill in the art for producing useful hapten-carrier conjugates is low. Therefore, the knowledge and level of skill does not supplement the omitted description because specific, not general, guidance is needed for the hapten-carrier conjugates. Since the disclosure fails to describe the common attributes or characteristics that identify all of the members of the genus or even a substantial portion thereof, and because the genus is vast and highly variant (e.g. linkers), the limited examples in the specification is insufficient to teach the entire subgenus.

The specification discloses only limited examples that are not representative of the claimed subgenus/species of a hapten-carrier conjugate comprising nicotine and pseudomonas exotoxin; nor do the claims recite sufficient structural feature(s) which is(are) common to members of the subgenus/species sufficient to demonstrate possession of the subgenus/species. Therefore, the teachings in the specification are general teachings relating without guidance as to the individual components of the product. In addition, there are numerous linkers that could be employed in the invention with little direction or guidance for one of skill in the art to make the claimed invention.

Furthermore, a lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559,

1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Also see In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) and Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). A "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. In the present specification, the laundry list of potential carriers and potential linkers would not reasonably lead one of skill in the art to the presently claimed subgenus/species particularly when the present specification focused on nicotine conjugated to BSA or CTB carriers (see Examples 26-30).

See pages 27-28 regarding laundry list of potential carriers: "Suitable carrier molecules are numerous and include, but are not limited to: Bacterial toxins or products , for example, cholera toxin B- 35 (CTB), diphtheria toxin, tetanus toxoid, and pertussis toxin and filamentous hemagglutinin, shiga toxin, pseudomonas exotoxin; Lectins, for example, ricin-B subunit, abrin and sweet pea lectin; Subvirals, for example, retrovirus nucleoprotein (retroNP), rabies ribonucleoprotein (rabies RNP), plant viruses (e.g. TMV, cow pea and cauliflower mosaic viruses), vesicular stomatitis virus-nucleocapsid protein (VSV-N), poxvirus vectors and Semliki forest virus vectors; Artificial vehicles, for example, multiantigenic peptides (MAP), microspheres; Yeast virus-like particles (VLPs); Malarial protein antigen; and others such as proteins and peptides as well as any modifications, derivatives or analogs of the above. To determine features of suitable carriers, initial experiments were performed using bovine serum albumin as a protein carrier."

See pages 35-36 regarding the laundry list of potential linkers: CJ 0, 1, 1.1, 1.2, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, and 11 "wherein n is an integer preferably selected from about 3 to about 20, more particularly about 3 to about 6; Y is preferably selected from the group consisting of S, O, and NH; and Q is preferably selected from the group consisting of: -H, -OH, -CH2, -CH3, -OCH3, -COOH, halogen, protein or peptide carrier, modified protein or peptide carrier, activated esters, such as 2-nitro-4-sulfophenyl ester and N-oxysuccinimidyl ester, groups reactive towards carriers or modified carriers such as mixed anhydrides, acyl halides, acyl azides, alkyl halides, N-maleimides, imino esters, isocyanate, isothiocyanate ; or another "branch" identified by its "CJ" reference number".

The laundry list of potential carriers and linkers would result in at least thousands of different compositions without reasonably leading one of skill in the art to the presently claimed subgenus/species as claimed. The expedient statements in the specification do not relate to an

adequate disclosure or how to make and use the claimed invention. Consequently, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to adequately describe the vast genus. Thus, Applicant does not appear to be in possession of the claimed genus.

Arguments and Response

17. Applicants' arguments directed to the rejection under 35 USC 112, first paragraph (written description), for claims 176 and 179 were considered but are not persuasive for the following reasons.

Applicants contend that the specification is "replete with examples of nicotine as the hapten used in the conjugate" and that working examples of nicotine conjugated to BSA or cholera toxin B are provided. Applicants appear to contend that pseudomonas exotoxin is not part of a laundry list because it is one of seven bacterial toxins described in the specification as potential carriers.

Applicants' arguments are not convincing since the bacterial toxins are a subgenus of the vast laundry list of carriers contemplated in the specification (see pages 27 and 28 of the originally filed specification).

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 176 and 179 are rejected under 35 U.S.C. 102(b) as being anticipated by Ennifar et al. U.S. Patent 6,232,082 issued May 15, 2001.

For present claims 176 and 179, Ennifar et al. teach nicotin-carrier conjugates wherein the carrier is Pseudomonas exoprotein A and various linkers (please refer to the entire specification particularly the abstract; columns 3-8, 11-12, 14; see SCORE search results).

Therefore, the teachings of Ennifar et al. anticipate the presently claimed invention.

Arguments and Response

20. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Ennifar et al. for claims 176 and 179 were considered but are not persuasive for the following reasons.

Applicants contend that the priority date for the present application is March 31, 1995.

Applicants' arguments are not convincing since the teachings of Ennifar et al. anticipate the hapten-carrier conjugate of the instant claims. See the priority section above.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 176 and 179 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 8-12, and 17-18 of U.S. Patent No. 5,876,727 in view of Glenn et al. U.S. Patent 5,980,898 with an effective filing date of November 14, 1996. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions as claimed in U.S. Patent No. 5,876,727 claim nicotine haptens conjugated to a carrier and pharmaceutical compositions of the hapten-carrier.

For present claims 169-172, U.S. Patent No. 5,876,727 claims a nicotine hapten-carrier conjugate comprising the structure shown in Figures 17b and 18 (e.g. nicotine) and side chains

(e.g. branch) of CJ 0, 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, and 11 (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claim 1). In addition, regarding pseudomonas exotoxin, Glenn et al. teach a transcutaneous immunization system comprising antigen/hapten, adjuvant, and/or carriers (i.e. antigens, adjuvants, and carriers can be the same or different molecules) wherein the hapten/adjuvant/carrier is preferably ADP-ribosylating exotoxins including Pseudomonas exotoxin and the composition can also contain hydrating agents, penetration enhancers, pharmaceutically acceptable additives, diluents, binders, stabilizers, preservatives, colorings, buffers, liposomes, etc. (i.e. pharmaceutically acceptable excipient, auxiliary agent, and supplementary active compound; please refer to the entire specification particularly the abstract; columns 1, 3-5, and 6-10; and Examples columns 16-29).

Therefore, the claims of U.S. Patent 5,876,727 render the presently claimed invention prima facie obvious.

Arguments and Response

23. Applicants' arguments directed to the rejection under nonstatutory obviousness-type double patenting over U.S. Patent 5,876,727 in view of Glenn et al. for claims 176 and 179 were considered but are not persuasive for the following reasons.

Applicants contend that the priority date for the present application is March 31, 1995.

Applicants' arguments are not convincing since the claimed invention of U.S. Patent 5,876,727 in view of Glenn et al. renders obvious the hapten-carrier conjugate of the instant claims. See the priority section above.

Conclusion

24. Applicant's amendment necessitated the new/revised ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JoAnne Hama can be reached on 571-272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639